

REMARKS

Claims 1-42 were pending in the subject application. In this amendment, Applicants have cancelled claims 36-40. Claims 1-35 and 41-42 are now pending in the subject application.

No new matter is added by these amendments, and Applicants respect request their entry.

I. Rejection of Claims 1-18 and 41-42 Based on Double Patenting

The Examiner rejected claims 1-18 and 41-42 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of U.S. Patent No. 7,119,061 to Stogniew et al. ("Stogniew") for the reasons set forth in the office action. The Examiner also rejected claims 20-40 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-22 of U.S. Patent No. 6,900,175 to Cavalari et al. ("Cavalari") in view of U.S. Patent No. 5,004,605 to Hershenson et al. ("Hershenson") for the reasons set forth in the office action.

Applicants will address the non-statutory double-patenting issues raised by the Examiner once the claims of the subject application are otherwise in condition for allowance.

II. Rejection of Claims 36-40 under 35 U.S.C. § 101

The Examiner rejected claims 36-40 under 35 U.S.C. § 101 for the reasons set forth in the office action. In particular, the Examiner asserts that the claims "are not supported by either a credible asserted utility or a well-established utility." The Examiner states that "the claims are directed to methods of preventing bacterial infection. The broadest reasonable interpretation of the term infection requires that one microorganism gain entry into cells of a host." The Examiner contends that "[t]here is no evidence that entry would be prevented, therefore that utility would not be credible."

Claims 36-40 have been cancelled, thereby rendering the Examiner's rejection moot.

In view of the above, Applicants request that the Examiner withdraw his rejection of claim 36-40 under 35 U.S.C. § 101.

III. Rejection of Claims 36-40 under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 36-40 under 35 U.S.C. § 112, first paragraph for the reasons set forth in the office action. In particular, the Examiner asserts that "since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention."

Claims 36-40 have been cancelled, thereby rendering the Examiner's rejection moot.

In view of the above, Applicants request that the Examiner withdraw his rejection of claim 36-40 under 35 U.S.C. § 112, first paragraph.

IV. Rejection of Claims 1-42 under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-42 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,750,509 to Malabarba et al. ("Malabarba et al.") in view of Hershenson for the reasons set forth in the office action. In particular, the Examiner states that "Malabarba et al disclose

an antibacterial agent dalbavancin (column 27, Table IV) and disclose the use of dalbavancin derivatives in combination with a stabilizing agent (column 28, lines 9-12)." The Examiner concedes that Malabarba et al does not "disclose the use of dextrose." Instead, the Examiner relies on Hershenson, stating that "since the use of dextrose as a stabilizing agent was well known in the art at the time the claimed invention was made as disclosed by Hershenson et al. (column 9, lines 21-24), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to combine dalbavancin with dextrose and to use the resulting composition for treating bacterial infections because such a person would have expected the resulting composition to be more stable." Applicants respectfully traverse.

As a preliminary matter, claims 36-40 have been cancelled, thereby rendering the Examiner's rejection of those claims moot.

Malabarba relates to derivatives of antibiotic A 40926. Malabarba states that "[t]he compounds of the present invention can be administered orally, topically or parentally, the parental administration route being preferred" (see col. 27, lines 46-48 of Malabarba). Malabarba states that "[c]ompositions for injection may take such forms as suspensions, solutions, or emulsions in oily or aqueous vehicles, and may contain formulatory agents such as suspending, stabilizing and/or dispersing agents" (see col. 28, lines 9-12 of Malabarba). However, Malabarba does not disclose or describe any particular class of stabilizing agents, let alone that the stabilizing agent should be a carbohydrate or even a sugar.

Hershenson relates to low pH pharmaceutical compositions containing "recombinant interferon-B protein (IFN-B) dissolved in an inert carrier medium comprising as a stabilizer/solubilizer in an effective amount either of glycerol or of polyethyleneglycol polymers" (see Abstract of Hershenson). Hershenson also states that his "compositions can further comprise an additional stabilizing agent, such as carbohydrate, for example, sucrose, dextrose, dextran, mannitol, sorbitol, inositol, fructose, galactitol, xylitol, lactose, and trahalose; or a non-carbohydrate, for example, human serum albumin (HAS) ..." (see col. 9, lines 21-26 of Hershenson). However, Hershenson does not teach or even suggest that carbohydrate stabilizing agents, if used, are preferred over the non-carbohydrate stabilizing agents. Moreover, even if a carbohydrate stabilizing agent was selected, Hershenson provides no guidance to select dextrose from the described list of carbohydrate stabilizing agents.

In summary, Hershenson mentions dextrose as one of many additional stabilizing agents, but Hershenson provides no teaching to select a carbohydrate stabilizing agent over a non-carbohydrate stabilizing agent, let alone to select dextrose from the among the other listed carbohydrate stabilizing agents. Thus, even if Malabarba describes composition comprising dalbavancin and a stabilizer, Malabarba in view of Hershenson provides no suggestion to make or use a composition comprising dalbavancin and dextrose as recited in the claims of the subject application.

"Where the claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires inter alia a consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior

art would have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). "[T]o have a reasonable expectation of success, one must be motivated to do more than merely vary all parameters or to try each of numerous possible choices until one possible arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006 (internal quotations omitted)).

Hershenson gives no indication that dextrose is critical to the preparation of a stable composition, let alone a stable composition comprising dalbavancin; thus, one of skill in the art would find no motivation in Hershenson to select dextrose as a stabilizer over the other described stabilizers as required by *Medichem, S.A.* And because Hershenson provides no motivation to select dextrose as a stabilizer over the other described stabilizers, one of skill in the art would not find a reasonable expectation of success in Malabarba in view of Hershenson to make or use a composition comprising dalbavancin and dextrose as required by *In re Vaeck* and *Medichem, S.A.* Therefore, claims 1-35 and 41-42 which recite a composition comprising dalbavancin and dextrose are not obvious over Malabarba in view of Hershenson for at least this reason.

In view of the above, Applicants respectfully submit that pending claims 1-35 and 41-42 (claims 36-40 having been cancelled) are not obvious over Malabarba in view of Hershenson, and request that the rejection of claims 1-35 and 41-42 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application. No additional fee is believed due. However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

If the Examiner wishes to comment or discuss any aspect of this application or response, Applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

Date: July 2, 2007

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